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Tel: 571-272-4683 Entered: February 11, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BRIAN L. **BATES**,
SCOTT E. BOATMAN, DAVID G. BURTON,
MICHAEL C. HOFFA,
DARIN G. SCHAEFFER, JASON S. STURGEON, and
ANTHONY O. RAGHEB
Junior Party
(Patent 7,803,149),

v.

JAMES J. **BARRY**,
and
MARIA PALASIS,
Senior Party
(Application No. 13/085,623),

Patent Interference No. 105,988
(Technology Center 1600)

Before RICHARD E. SCHAFER, SALLY GARDNER LANE, and DEBORAH KATZ, *Administrative Patent Judges*.

LANE, *Administrative Patent Judge*.

Judgment – Bd. R. 127(a)

In view of the Decision on Motions (Decision, Paper 238), it is

ORDERED that judgment on priority as to Count 1 (Declaration (Paper 1) at 4), the sole count of the interference, is entered against senior party James J. Barry, and Maria Palasis;

FURTHER ORDERED that claims 27, 29-31, and 34-36 of senior party Barry application 13/085,623, which claims correspond to Count 1, are FINALLY REFUSED; 35 U.S.C. § 135(a); [1]

FURTHER ORDERED that the parties are directed to 35 U.S.C. § 135(c) and to Bd. R. 205 regarding the filing of settlement agreements;

FURTHER ORDERED that a copy of this judgment shall be entered into the administrative record of the involved junior party patent and the involved senior party application; and

FURTHER ORDERED that, if a party seeks judicial review, the party must file a notice with the Board within seven days of initiating judicial review. Bd. R. 41.8(b). We direct the parties' attention to *Biogen Idec MA, Inc., v. Japanese Foundation for Cancer Research*, 2014 WL 2167677 (D.Mass. 2014).

1 Any reference to a statute in this Judgment is to the statute that was in effect on March 15, 2013 unless otherwise indicated. See Pub. L. 112-29, § 3(n), 125 Stat. 284, 293 (2011).

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LANE, *Administrative Patent Judge*.

Decision – Motions - Bd. R. 121(a)

I. Introduction

An interference was declared under 35 USC 135(a)[1] on 23 January 2014 between junior party Bates[2] and senior party Barry.[3] (Declaration, Paper 1). The following motions are before us for decision.

Bates Motions

1. Bates Motion 2 for judgment on the basis that the Barry claims are unpatentable for lack of sufficient support under the first paragraph of 35 U.S.C. § 112. (Bates Motion 2, Paper 93).

2. Bates Motion 3 challenging the benefit accorded to Barry in the declaration of interference. (Bates Motion 3, Paper 89).

3. Bates Motion 4 seeking to substitute a Count for the current Count. (Bates Motion 4, Paper 90).

Bates also filed Bates Motion 1 (Bates Motion 1, Paper 35) seeking judgment on the basis that Barry lacked standing in the interference because its claims are barred under 35 U.S.C. § 135(b)(1). We denied that Motion. (Decision on Bates Motion 1, Paper 111 and Decision on Rehearing, Paper 121).

Barry Motions

1. Barry Motion 1 for judgment on the basis that the Bates claims are unpatentable for lack of sufficient support under the first paragraph of 35 U.S.C. § 112. (Barry Motion 1, Paper 49).

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1 Any reference to a statute in this Decision is to the statute that was in effect on March 15, 2013 unless otherwise indicated. See Pub. L. 112-29, § 3(n), 125 Stat. 284, 293 (2011).

2 The named Bates inventors are Brian L. Bates, Scott E. Boatman, David G. Burton, Michael C. Hoffa, Darin G. Schaeffer, Jason S. Sturgeon, and Anthony O. Ragheb.

3 The named Barry inventors are James J. Barry, and Maria Palasis.

2. Barry Motion 2 for judgment on the basis that the Barry claims are unpatentable under 35 U.S.C. § 102 and/or § 103 over prior art. (Barry Motion 2, Paper 88).

3. Barry Motion 3 seeking to add an additional Bates patent to the interference. (Barry Motion 3, Paper 86).

4. Barry Miscellaneous Motion 5 seeking to exclude certain evidence. (Barry Motion 5, Paper 221).

Barry also filed Barry Miscellaneous Motion 4 seeking the relief that one of its witnesses not be required to answer certain questions on the basis that the answers might reveal privileged material. (Barry Miscellaneous Motion 4, Paper 172). That Motion was dismissed. (Decision on Barry Miscellaneous Motion 4, Paper 175).

We GRANT Bates Motion 2 and DISMISS the remaining motions before us.

Background

The Count of the interference is directed generally to a method of delivering the drug paclitaxel to a patient's blood vessel using a balloon catheter having the drug on its surface. Paclitaxel is a known drug and is used as an anti-cancer and anti-angiogenic agent. (Bates patent , Ex 2001, at 12:22-24).

Both parties describe balloon catheters for delivering the drug paclitaxel. In each case the balloon catheters are coated with the drug to allow for its delivery. In the balloon catheters of Barry the drug is placed in a containment polymer to allow for controlled release of the drug. (Barry specification, Ex 2002, at, e.g., ¶ 0045). In the balloon catheters of Bates, however, the drug is not placed into a containment polymer. (Bates patent at 5:45-50). According to the Bates

specification, "[t]he specific improvement of the present invention entails attaining a desired surface roughness, or texturing on the surface of the device…and applying the bioactive material directly to that roughened or textured surface without the need of any further overlying or containment layer or coating." (Bates patent at 5:19-24).

II. Findings of fact

The record supports the following findings of fact by a preponderance of the evidence.

Bates

1. Junior party Bates is involved in the interference on the basis of patent 7,803,149, issued on 28 September 2010 from application 10/618,977, filed 14 July 2003. (Declaration at 3).

2. The Bates real-parties-in-interest are said to be Cook Medical Technologies and William A. Cook Australia Pty Ltd. (Bates Notice of Real-Partes-in-Interest, Paper 4).

3. All of the claims of the Bates patent, claims 1-23, correspond to the Count. (Declaration at 5).

4. Bates was accorded the following benefit as to Count 1.

US 60/395,434, filed 12 July 2002

(Declaration at 5).

Barry

5. Senior party Barry is involved in the interference on the basis of application 13/085,623, filed 13 April 2011. (Declaration at 4).

6. The Barry real party-in-interest is said to be Boston Scientific Scimed, Inc. (Barry Notice of Real-Party-in-Interest, Paper 10).

7. All of the claims of the Barry involved application, claims 27, 29-31, and 34-36, correspond to the Count. (Declaration at 5).

8. Barry was accorded the following benefit for Count 1:

US 11/833,717, filed 03 August 2007

US 11/188,850, filed 26 July 2005

US 09/978,763, filed 18 October 2001

US 09/172,026, filed 14 October 1998

(Declaration at 5 and Redeclaration, Paper 21, at 2)

The Count

9. The sole Count of the interference, Count 1, is:

Claim 1 of Bates or claim 27 of Barry.

(Declaration, Paper 1, at 4).

10. Claim 1 of Bates reads:

> A method of delivering paclitaxel to an inner wall of a blood vessel of a patient from an implantable medical device having an expandable balloon with the paclitaxel on an outer surface of the balloon, the method comprising the steps of:
>
> (1) providing an angioplasty balloon having a dried layer containing the paclitaxel on the outer surface of the balloon, the balloon being free of a coating

atop the dried layer, the balloon being free of a time-release layer, the balloon being free of a containment material and the balloon being free of a containment layer; and further wherein the balloon has folds, and portions of the dried layer containing paclitaxel are positioned in the folds;

(2) advancing the balloon within the blood vessel to a treatment site within the blood vessel;

(3) inflating the balloon at the treatment site to contact the balloon with an inner wall of the blood vessel;

(4) maintaining the inflated balloon in contact with the inner wall of the blood vessel so as to transfer paclitaxel to the inner wall of the blood vessel;

(5) deflating the balloon after said maintaining; and

(6) removing the deflated balloon from the blood vessel.

(Bates Clean Copy of Claims, Paper 6, numbering and indentations added).

11. Barry claim 27 reads:

A method of delivering paclitaxel to an inner wall of a blood vessel from a balloon catheter having an expandable balloon with a coating on an outer surface of the balloon, the method comprising:

(1) providing a balloon catheter including a balloon with a dried coating consisting of paclitaxel or a mixture of paclitaxel with another bioactive agent, the dried coating being free of any additional coating and solvent atop the dried coating;

(2) advancing the balloon within the blood vessel to a treatment site;

(3) inflating the balloon to directly contact the paclitaxel or mixture of paclitaxel with another bioactive agent with an inner wall of the blood vessel; and

(4) delivering the paclitaxel or mixture of paclitaxel with another bioactive agent to the inner wall of the blood vessel while maintaining the paclitaxel or mixture of paclitaxel with another bioactive agent in direct contact with the inner wall of the blood vessel while the balloon is inflated.

(Barry Clean Copy of Claims, Paper 9, numbering and indentations added).

12. The Barry involved claims were presented in the involved Barry application after issuance of the Bates patent. (Barry published application, Ex 2002 and application as filed, Ex 2003).

13. Thereafter Barry suggested the interference under Bd. R. 202(a), stating that Bates claim 1 and Barry claim 27 "define substantially the same invention. (Request for Interference, Ex 2004, at 16-18).

14. In the Request Barry stated that its claimed coating "excludes a release layer, a containment material, and a containment layer" and that the coating is limited to "paclitaxel or a mixture of paclitaxel with another bioactive agent" and "excludes anything else from that layer." (Request for interference at 13).

15. The parties agree that a "coating" is a substance placed on the surface of a substrate such as a balloon surface. (Bates Motion 2, SMF[4] 1, admitted by Barry, and Bates Motion 1 at 3:5-7).

16. The parties agree that a "bioactive agent" is a substance that produces a

4 Statement of Material Fact.

desired biological or pharmaceutical result for a patient. (Bates Motion 2, SMF 2, admitted by Barry).

17. The parties agree that the Barry device has a polymer coating. (Bates Motion 2, SMF 3, relevant portion admitted by Barry).

18. We understand that the polymer of Barry (which we also refer to herein as a containment polymer) is used to provide a containment, i.e., controlled or time release, feature to the balloon catheter. (Bates Motion 2, SMF 4, admitted by Barry).

19. When speaking specifically of balloon catheters the Barry specification states:

> When an expandable catheter is chosen as the medical device of the present invention, the expandable portion is preferably a balloon, in which case the drug is placed in the polymer for controlled release of the drug upon expansion of the balloon against a body lumen.
>
> (Barry specification at ¶ 0045).

20. Bates on the other hand specifically excludes polymers and other materials that might provide a containment function. (Bates Motion 2, SMF 14 (denied by Barry but on the basis that the lack of containment polymer is not novel)).

The testimony

21. Dr. Stephen R. Byrn provided testimony, further described in the Discussion below, on behalf of party Bates regarding, *inter alia*, what the Bates and Barry specifications would have conveyed to one skilled in the art. (Byrn Declaration, Ex 2014).

22. Dr. Byrn testified that he is a Professor of Medicinal Chemistry and that he has been the head of the Department of Medicinal Chemistry and

Pharmacology, and the head of the Department of Industrial and Physical Pharmacy, at Purdue University. (Bryn Declaration at 2).

23. Dr. Byrn testified that he has been engaged in study, research and teaching in the field of physical, organic and pharmaceutical chemistry for more than 40 years and has particular experience with solid state chemistry of drugs, including pharmaceutical coatings applied to intravascular medical devices.

24. Based on his education, professional experience and other accomplishments set forth in his Declaration and attached curriculum vitae (Exhibit A to the Byrn Declaration), we determine that Dr. Bryn is qualified to testify about issues relevant to this interference.

25. Dr. Steve Kangas provided testimony, further described in the Discussion below, on behalf of Barry regarding, *inter alia*, his opinions about what the Barry specification would have conveyed to one skilled in the art based on testing performed under his supervision seeking to replicate Example 9 of the Barry specification. (Kangas Declaration, Ex 1066).

26. Dr. Kangas testified that he has a Ph.D. in Polymer Chemistry and has been working at Boston Scientific Scimed, Inc., the Barry real-party-in-interest, since 2001.

27. Dr. Kangas testified that he is a Fellow at the Interventional Cardiology Research and Development Department at Boston Scientific Corporation.

28. Dr. Kangas testified that from 1996 to 2001 he worked as a Chemist in the areas of formulation and characterization of photoreactive imageable coatings.

29. Based on his education, professional experience and other accomplishments set forth in his Declaration and attached curriculum vitae (Appendix A to the Kangas Declaration), we determine that Dr. Kangas is qualified to testify about

issues relevant to this interference.

30. Dr. W. Mark Saltzman has presented testimony, further described in the Discussion below, on behalf of Barry regarding, *inter alia*, what the Barry specification would have conveyed to one skilled in the art. (Saltzman Declaration, Ex 1006).

31. Dr. Saltzman has a Ph.D. in medical engineering, has extensive teaching experience in chemical and biomedical engineering and extensive research experience in drug delivery. (Saltzman Declaration at ¶¶1-12).

32. Based on his education, professional experience and other accomplishments set forth in his Declaration we determine that Dr. Saltzman is qualified to testify about issues relevant to this interference.

III. Discussion

Bates Motion 2 (based on lack of written description and/or enablement)

We turn first to Bates Motion 2 as it presents a threshold issue that, if resolved in Bates' favor, might deprive Barry of standing in the inference. In particular such a threshold issue is presented where, e.g., an applicant suggests an interference under Bd. R. 202(a), as Barry did here, yet its claims are found to lack written description support. Bd. R. 201.

As the moving party, Bates has the burden of proof to show that it is entitled to the request relief. Bd. R. 121(b).

Written Description

In its Motion 2, Bates argues that the Barry specification does not provide written description support for certain features found in the Barry claims such that the Barry claims are not patentable to Barry. (Bates Motion 2 at 1).

"To satisfy [the written description] requirement, the specification must describe the invention in sufficient detail so 'that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.'" *In re Alonzo*, 545 F.3d, 1015, 1019 (Fed. Cir. 2008), citing *Lockwood v. Am. Airlines, Inc*., 107 F.3d 1565, 1572 (Fed.Cir.1997). We thus consider what the specification reasonably would have conveyed to one of ordinary skill in the art in evaluating whether the specification provides sufficient written description for the claimed invention. *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125 (Fed. Cir. 2004).

Bates argues that, as the Barry claims were substantially copied from the claims of the involved Bates patent, the claim construction principle set forth in *Agilent Techs. Inc. v. Affymetrix, Inc.*, 567 F.3d 1366 (Fed. Cir. 2009) is applicable. Accordingly, argues Bates, we must look to see if the Barry specification describes the subject matter that was substantially copied, construing that subject matter in the context of the Bates specification. (Bates Motion 2 at 1:6-13). Barry does not disagree that *Agilent* applies and argues that its specification provides description for all the claimed features when its claims are construed in accordance with Bates' construction. (Barry Opposition 2 at 1:4-8).

We agree with the parties and construe the Barry claims in the context of the Bates specification for purposes of evaluating whether the Barry specification provides written description support. (*Agilent* at 1375 ("To be clear, as the court explained in ***Rowe***, when a party challenges written description support for an interference count or the copied claim in an interference, the originating disclosure

provides the meaning of the pertinent claim language.")[5]; See also *Tobinick v. Olmarker*, 753 F.3d 1220, 1224 (Fed. Cir. 2014), citing *Robertson v. Timmermans*, 603 F.3d 1309, 1312 (Fed. Cir. 2010) ("In interference proceedings, a disputed claim is construed in the context of its originating disclosure rather than the interfering application".) While the Barry claims are not verbatim copies of the Bates claims, in suggesting the interference, Barry represented that its claims define the same or substantially the same invention as the claims of Bates. (See Suggestion of Interference at, e.g., 16-17, including chart comparing Bates claim 1 to claim 27 and representation that "claims define substantially the same invention."). We believe it is correct to construe the claims in dispute in view of the Bates specification for the reason set forth in *Agilent*, i.e., because we are evaluating whether Barry has sufficient basis, i.e., sufficient written description, to challenge Bates' priority of invention as to the substantially copied subject matter. (See *Agilent* at 1375)("Stated more directly, does Besemer have adequate basis to copy Schembri's claim and thereby challenge Schembri's priority of invention?"); *See also Ex parte Smart*, http://www.uspto.gov/ip/boards/bpai/decisions/inform/fd09-015036.pdf (PTAB 2010) (applying *Agilent* after Applicant suggested an Interference representing its added claims to be "the same or substantially the same subject matter" as published claims).

Bates argues that the claimed balloon catheters exclude a containment polymer as part of the coating. In suggesting the interference, Barry seemed to

5 For purposes of evaluating other challenges to patentability, e.g., prior art under 35 U.S.C. § 102 or § 103, it is appropriate to construe the claims in view of the specification in which they appear. See *Agilent* at 1375).

agree stating that, because of the "closed language" of its claims, the coating "excludes a release layer, a containment material, and a containment layer" and that the coating is limited to "paclitaxel or a mixture of paclitaxel with another bioactive agent" and "excludes anything else from that layer." (Request for interference at 13). Bates argues that the claimed balloon catheters are not described in the Barry specification because the coatings described in the Barry specification require a containment polymer in addition to the paclitaxel and any additional bioactive agent. (Bates Motion 2 at 8:3-18).

We construe the Barry claims, as viewed in the context of the Bates application, as limited to a "coating" that does not have within it a containment polymer.[6] In this regard we credit Dr. Byrn's testimony that the Bates description is directed to "application of a paclitaxel layer by itself to a device, including a balloon catheter" and "without layers or materials designed to extend release of the paclitaxel". (Bryn Declaration at ¶ 21). Dr. Byrn's testimony is consistent with the language of the Bates specification, including the Bates claims, indicating a device that is not coated with any containment polymer material. (See, e.g., Bates patent at 3:9-19, 14:5-13, and claim 1). Moreover, Barry agrees that the Bates' specification describes devices that exclude any containment polymer coating. (Bates Motion 2, SMF 14 (denied by Bates but on basis that the lack of containment polymer is not novel).

Even though Barry concedes that the coatings described by its specification include a polymer, Barry takes the position that it nevertheless describes the

6 Construing the Barry claims in view of the Barry specification may raise a question of whether an interference-in-fact exists. See Bd. R. 203(a). Since this issue has not been raised in the briefing though we do not consider it.

claimed coatings. In particular, Barry argues that it describes balloon catheters that have a polymer coating and then a separate and distinct paclitaxel coating such that a coating "consisting of" paclitaxel is present. (Barry Opposition 2 (Paper 139) at 2, citing to, e.g., Example 9 of its specification as well as ¶¶ 39-41, 72 and 73).

We are not persuaded by Barry's argument because we conclude that the Barry claims, as construed in the context of the Bates specification, are directed to a balloon catheter that is not coated with any containment polymer material. Such a balloon catheter is not described by Barry and thus, we find that Bates has shown a lack of written description for the claimed subject matter.

Further, even if we were to construe the Barry claims in such a way that the balloon catheter may have a coating of containment polymer that is separate from the coating consisting of paclitaxel, we are not persuaded by Barry's argument that its specification describes such a device.

The medical devices of Barry contain paclitaxel that is "[i]ncorporated into" the polymer coatings (Barry specification at ¶ 0009) to form a "drug-impregnated polymer coating." (Barry specification at ¶ 0032).

Barry, in arguing that the paclitaxel need not be within the containment polymer, urges that the Barry specification "never states or implies that the reason for the polymer layer on a balloon is to contain or control the paclitaxel." (Barry Opposition 2 at 3:10-11). Barry is incorrect. As Bates has pointed out, the Barry specification states:

> When an expandable catheter is chosen as the medical device of the present invention, the expandable portion is preferably a balloon, *in which case the drug is placed in the polymer for controlled release of the drug* upon expansion of the balloon against a body lumen.

(Bates Reply 2 referring to Barry specification at ¶ 0045, emphasis added).

Barry argues though that it is the "one or more additional layers" of a "preferred embodiment" that modulates release of the drug. (Barry Opposition 2 at 3:10-16, referring to Ex 2002 at ¶ 43). The embodiment referred to by Barry is one where the medical device has been "previously coated with a polymer/drug agent in accordance with the present invention" and an additional release rate-modifying or modulating layer may be applied in a subsequent coating step. However, Barry has not explained why the optional addition of second polymeric coat to control or modulate release of the drug means that the required polymeric coat does not also work to control release of the drug. Indeed, as we have noted, the specification states that, specifically in the case of a balloon catheter, "the drug is placed in the polymer for controlled release." (Barry specification at ¶ 0045).

As Barry has not pointed to express support for a separate paclitaxel coating, we understand Barry's argument to be that the specification inherently describes such a separate coating. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. 'Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, (Fed. Cir. 1999) (citations omitted).

Barry argues that replication of Example 9 of its specification demonstrates that the paclitaxel forms a "discrete layer" on the balloon catheter. (Barry Opposition 2 at 2:16-20, referring to Kangas Declaration at ¶¶ 12-15). In his

testimony, Dr. Kangas describes preparation and testing of balloons said to have been performed under his supervision and in accordance with the "drip method" of Example 9 of the Barry specification. Dr. Kangas testified that, based upon his review of data obtained from analysis of the "drip method" balloons, he concluded that these balloons have "a discrete layer of paclitaxel residing on the polyurethane [polymer] coating." (Kangas Declaration at ¶ 15).

Because Example 9 is lacking in details of how to form the balloon catheter it discusses, Dr. Kangas testified that it was necessary for him to "fill in the gaps" to make what is said to be a balloon catheter according to Example 9. (Deposition Transcript of Kangas (Ex 2056) at 131:21-24). Dr. Kangas conceded that he had to choose such details as the type of polyurethane polymer, dip speed and time, and ethanol grade. (Deposition Transcript of Kangas at e.g., 131:21-24; 40:5-42:19; 52:8-54: 25; 58:9-12; 59:12-20; 61:1-24; 65:17- 66:10; 67: 15-25; 68:1-23;111:9-112:1; 113:1-115:17;133:3-135: 25.) Dr. Kangas stated that he did not know what Barry meant by the "dripping" method of Example 9 so he opted to use a method that resulted in the spreading of the drug solution. (Deposition Transcript of Kangas at 134:22-135:9; 113:1-115:17). Dr. Kangas testified that he spun the balloons at a high speed to form a layer of the solution even though spinning is not called for in Example 9. (Deposition Transcript of Kangas at 67:15-25 and 68:1-11). Despite the need to fill in the gaps, Dr. Kangas conceded that he did not read the entire Barry specification and that "[he] reviewed Example 9, and….kind of read through some of the other examples" and the claims but "didn't go into detail on the specification."[7] (Deposition Transcript of Kangas at 31:17-32:1).

7 In his testimony Dr. Kangas referred to the '166 patent which we understand to be Barry patent 6,306,166 (Ex 1008) which issued from Barry benefit application 09/172,026 and which

The need for Dr. Kangas to "fill in the gaps" as he did signifies that Example 9 does not provide enough information for us to find that a separate paclitaxel layer is inherently described by the Example. Further weighing against such a finding is the express language of Example 9 (and elsewhere in the specification) that paclitaxel is "loaded" into the polymer. (Example 9 at ¶ 0071 and ¶ 0045).

Barry urges that Dr. Kangas simply chose parameters and techniques that one of ordinary skill in the art would have used to replicate the example. (Barry Response to Additional Material Facts, Paper 218, in response to SMF 38 and 39). Accepting that Dr. Kangas made choices within the options that were known to those skilled in the art, we have not been directed to evidence sufficient to show that one skilled in the art necessarily would have made the particular choices that Dr. Kangas made. Further, as Dr. Kangas conceded, he did not read the entire Barry specification and thus his choices were not informed by what the Barry specification as a whole would have directed to one skilled in the art.

Barry further argues that other data in its specification shows "immediate ***and*** sustained release of paclitaxel from a paclitaxel coated balloon" which, according to Barry, "would indicate to one of skill in the art that a layer of drug is present at the outer surface of the balloon." (Barry Opposition 2 at 2:16-3:3, referring to Barry specification at Figs. 3a, 3b, 9 and Table II (Example 6) and Fifth Declaration of Saltzman (Ex 1067) at ¶¶ 18 and 19, original emphasis).

Dr. Saltzman testified:

> It is my opinion that a person of ordinary skill as of October 1998 would have understood such immediate release to indicate that a layer of paclitaxel is present at the outer surface of the balloon. Such data also demonstrate that the polymer layer underneath the drug layer is

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we understand has the same specification as the involved Barry application.

not a "release rate-modifying layer.

(Saltzman Declaration at ¶ 18, referring to the Barry specification at Figures 3a, 3b, and 9, Table II, and ¶0043).

Dr. Saltzman also testified that:

> In order to allow extended release of paclitaxel from a balloon, the blood vessel of a patent would be occluded for a period of days, causing complications such as ischemia of the surrounding tissues. Accordingly, as of October 1998, one of ordinary skill in the art would have recognized that prolonged implantation of an inflated angioplasty balloon would be undesirable and that Barry teaches balloon embodiments capable of immediate release of paclitaxel.

(Saltzman Declaration at ¶ 19).

Dr. Saltzman refers to figures and tables in the Barry specification but fails to provide much explanation of how he reached his conclusions based on the figures and tables. For example, at Table II "[t]he amount of paclitaxel released in the pig bloodstream, as calculated from the amount of *paclitaxel loaded into* the [polyacrylic acid-based] coating minus that *extracted from* the coating after delivery" is reported. Table II reports that after 1 minute 63% of the loaded paclitaxel is released in the bloodstream and that after five minutes 68% of the drug is released. (Barry specification at Example 6 at ¶ 0062 and Table II, emphasis added).

Lacking from Dr. Saltzman's testimony is sufficient explanation of why the release rate of the drug indicates that a separate layer of paclitaxel is formed, particularly when the example itself states that the paclitaxel is "loaded into" the polymer and is "extracted from" the polymer. Elsewhere in the specification, Barry explains that in the balloon catheter "the drug-impregnated polymer coating"

contacts the lumen wall and then "[t]he drug is released from the polymer as it slowly dissolves" which serves to limit drug exposure to the rest of the body. (Barry specification at ¶32). Further, Bates points to evidence that it was known in the art that drug/polymer coated medical devices were known to, at times, have a rapid burst release of the drug. (Bates Reply 2 at 3:7-12, referring to Ex 1055 at 124-125, Ex 2051 at 248, Ex 1067 at ¶11, and Ex 2052 at ¶7).

Bates further argues that the Barry specification does not provide sufficient description for the claim limitation "wherein the balloon has folds, and [wherein] portions of the dried layer are positioned in the folds." (Bates Motion 2 at 9-11). Bates also argues that the Barry specification does not provide sufficient description for the limitations of the claims directed to the absence of solvent in the coating, i.e., "dried coating being free of…solvent atop the dried coating," "dried coating without solvent," and "substantially free of solvent". (Bates Motion 2 at 8-9). None of these other limitations is argued by Bates to result in unpatentability of all the Barry involved claims. We already determined that all of the Barry involved claims are unpatentable for reasons stated above. Accordingly, we exercise our discretion to not consider the arguments regarding these other limitations.

Enablement

Bates argues that the Barry application could not have taught how to perform or use the claimed methods or the items recited in those methods since the Barry specification does not show that the inventors had in mind the claims now at issue. (Bates Motion 2 at 16:10-16).

The written description requirement is separate and distinct from the enablement requirement. *Ariad Pharm., Inc. v. Eli Lilly and Co.,* 598 F.3d 1336,

1341(Fed. Cir. 2010). To satisfy the enablement requirement, the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without requiring "undue experimentation". *In re Wright*, 999 F.2d 1557, 1561, (Fed. Cir. 1993). "The determination of what level of experimentation is 'undue,' so as to render a disclosure non-enabling, is made from the viewpoint of persons experienced in the field of the invention." *Elan Pharmaceutical, Inc. v. Mayo Foundation*, 346 F.3d 1051, 1055 (Fed Cir. 2003), citing *Enzo Biochem, 188 F.3d at 1373–74* as discussing evidence of enablement and nonenablement in an unpredictable field of biotechnology. Thus, as with written description, we consider the viewpoint of persons skilled in the art in determining whether the disclosure is sufficiently enabling of the claimed invention. Factors that are considered in the enablement inquiry include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Enablement is evaluated as of the application filing date. *In re Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995). We therefore evaluate Barry's enablement from the view point of one skilled as of 13 April 2011, the filing date of the Barry application. Bates' argument addresses what the Barry specification expressly discloses and does not provide a sufficient discussion of the state of the prior art including what one skilled in the art would have known at the time that would have contributed to the enablement of the Barry claims. For example, the Bates patent issued prior to the Barry filing date and so its teachings were available to one

skilled in the art.

Bates did not direct us to sufficient evidence to establish that the claims were not enabled as of the filing date of the involved Barry specification. Bates did not meet its burden of proof as to the enablement issue. Bd. R. 121(b).

We GRANT Bates Motion 2 for judgment on the basis that the Barry claims are unpatentable for lack of sufficient support under the first paragraph of 35 U.S.C. § 112.

Barry Miscellaneous Motion 5 seeking to exclude certain evidence.

Barry moves to exclude certain evidence on the basis that the evidence is "inadmissible as hearsay, being made by an unqualified expert witness, and/or lacking proper foundation or authentication." (Barry Miscellaneous Motion 5 at 1). In particular, Barry seeks to exclude portions of Exhibits 2033 and 2034.

Exhibit 2033 is a Response filed on 30 June 2014 in European Application No. 10 728 079.4. Exhibit 2034 is the second declaration of Dr. Byrn. (Bates Exhibit List, Paper 233).

In deciding Bates Motion 2, we did not rely on either the testimony of Dr. Byrn that was provided in this second declaration or the Response in the European Application. Accordingly, we need not and do not decide whether the evidence should be excluded.

Barry Miscellaneous Motion 5 is DISMISSED as moot.

Summary

We grant Bates Motion 2 as Bates has shown that the involved Barry claims, lack sufficient written description. As Barry does not have standing in the interference (Bd.R. 201), we do not consider the other motions before us.

IV. Order

It is

ORDERED that Bates Motion 2 is GRANTED,

FURTHER ORDERED that Bates Motions 3 and 4 and Barry Motions 1, 2, 3 and Barry Miscellaneous Motion 5 are DISMISSED; and

FURTHER ORDERED that judgment will be entered against Barry in a separate paper.

cc (via electronic):

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